

PATENT COOPERATION TREATY

From the:
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

To:

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PCT

WRITTEN OPINION

(PCT Rule 66)

SAW

Date of mailing (day/month/year) 21.08.2000	
Applicant's or agent's file reference P023523WO	REPLY DUE within 3 month(s) from the above date of mailing
International application No. PCT/GB99/03979	International filing date (day/month/year) 29/11/1999
Priority date (day/month/year) 27/11/1998	
International Patent Classification (IPC) or both national classification and IPC C12N15/62	
Applicant CELLTECH THERAPEUTICS LIMITED et al.	

1. This written opinion is the **first** drawn up by this International Preliminary Examining Authority.
2. This opinion contains indications relating to the following items:
 - I ☒ Basis of the opinion
 - II ☐ Priority
 - III ☐ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
 - IV ☐ Lack of unity of invention
 - V ☒ Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
 - VI ☐ Certain document cited
 - VII ☐ Certain defects in the international application
 - VIII ☒ Certain observations on the international application
3. The applicant is hereby **invited to reply** to this opinion.

When? See the time limit indicated above. The applicant may, before the expiration of that time limit, request this Authority to grant an extension, see Rule 66.2(d).

How? By submitting a written reply, accompanied, where appropriate, by amendments, according to Rule 66.3. For the form and the language of the amendments, see Rules 66.8 and 66.9.

Also: For an additional opportunity to submit amendments, see Rule 66.4.
For the examiner's obligation to consider amendments and/or arguments, see Rule 66.4 bis.
For an informal communication with the examiner, see Rule 66.6.

If no reply is filed, the international preliminary examination report will be established on the basis of this opinion.
4. The final date by which the international preliminary examination report must be established according to Rule 69.2 is: **27/03/2001**.

Name and mailing address of the international preliminary examining authority:

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Authorized officer / Examiner

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Formalities officer (incl. extension of time limits)
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I. Basis of the opinion

1. This opinion has been drawn on the basis of (*substitute sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this opinion as "originally filed".*):

Description, pages:

1-20 as originally filed

Claims, No.:

1-7 as originally filed

Drawings, sheets:

1/10-10/10 as originally filed

2. The amendments have resulted in the cancellation of:

- ☐ the description, pages:
☐ the claims, Nos.:
☐ the drawings, sheets:

3. This opinion has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)):

4. Additional observations, if necessary:

V. Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims	
Inventive step (IS)	Claims	1-7
Industrial applicability (IA)	Claims	

2. Citations and explanations

see separate sheet

VIII. Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

see separate sheet

Re Item V

1. The documents mentioned in this written opinion are numbered as in the International Search Report (ISR), i.e. D1 corresponds to the first document of the ISR etc.
2. As the priority document for the application was not available at the time of drafting of the present written opinion, it is established under the assumption that the entire subject-matter is entitled to the claimed priority. If this is not the case, the 'P' document cited in the search report may have to be considered for novelty and/or inventive step. This document (published by the inventors) would be detrimental to most, if not all, of the claimed subject-matter (Article 33(2), (3) PCT).
3. The present application does not satisfy the criterion set forth in Article 33(3) PCT because the subject-matter of **claims 1-7** does not involve an inventive step. D1 is considered to represent the closest prior art and discloses the determination of a specifically cleavable by copper (II) ions.
The difference between D1 and the subject matter of **claims 1-7** of the present application is the use of this site for the creation of an DNA encoding a hybrid protein, which can be cleaved after expression vector.
Starting from D1, the underlying technical problem is the provision of a DNA which expresses cleavable fusion proteins, which are specifically cleaved by copper II ion.
The subject-matter of the claims referred to above is considered to solve this problem. However, the solution proposed in **claims 1-7** of the present application cannot be considered as involving an inventive step (Article 33(3) PCT) for the following reasons:
DNA expressing hybrid proteins, which can be cleaved by specific proteases are well known in the prior art see for example D3, which discloses the use of the coagulation factor X sequence specific site (D3, Abstract). Thus a skilled person would try also use the teaching of D1 in order to solve the above formulated problem. Consequently, **claims 1-7** do not fulfil the requirements of Article 33(3) PCT.

Re Item VIII

4. A DNA sequence encoding a protein (see e.g. **claim 1**) - being a chemical product - has to be characterised e.g. by its sequence or as a product by process, but not merely by its function. According to the PCT-Guidelines C III 4.7. and 4.7.a, the area defined by the claims must be as precise as the invention allows. That means that claims which attempt to define the invention, or a feature thereof, by a result to be achieved, should not be allowed.



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One of these labels should be affixed to a prominent place in the upper part of the letter or form etc. which you are filing.